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Section I (Remarks)**A. Summary of Examiner Interview Conducted on August 23, 2007**

The undersigned extends appreciation to the Examiner for granting an in-person Examiner Interview on August 23, 2007. Although no agreement was reached with respect to patentability of the claims, it was helpful to discuss various issues presented by the application.

For comparison purposes as the interview, Applicant provided samples of products embodying the subject matter of various pending claims (including balloons formed of peripherally bonded half-sections of multilayer film and being non-pillowed and spheroidal in shape when inflated), along with samples of other products not embodying critical features of the claims – i.e., with such other products representing balloons formed of peripherally welded circular sheets of multilayer film, with the other products being dramatically pillowed (i.e., including pronounced involutions along the peripheral seam thereof) upon inflation. Comparison between U.S. Patent No. 6,976,950 to Connors ("Connors") and the pending claims was discussed. The Declaration of Tilak Shah under 37 CFR 1.132, and the lack of consideration of same by the Examiner in formulating rejections stated in the July 2, 2007 Office Action, was further discussed.

The Examiner suggested that the only difference between the pending claims and Connors is one of shape, and that mere changes in shape over the prior art represent design choices that are to be given little or no patentable weight, such that the limitation "non-pillowed and spheroidal in shape [when in an inflated state]" fails to patentably distinguish Connors. The undersigned pointed out that Connors provided no teaching or derivative basis for any multi-layer laminate balloon structure that in an inflated state is non-pillowed and spheroidal in shape. The Examiner further stated that the limitation "formed from two vacuum thermoformed half-sections of a multilayer film" would be given no patentable weight in a device claim, as such limitation was directed to a process. The undersigned indicated that the pending claims were patentably distinct over Connors without the "vacuum thermoformed" limitation.

The Examiner stated that she was confident that she could find another patent – whether utility or design – showing a non-pillowed balloon. The undersigned challenged the Examiner to find a prior art reference embodying not only a non-pillowed balloon, but also a balloon formed from

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two half-sections of peripherally bonded multilayer film as claimed – given Applicant's well-founded understanding that the only way to form such a structure was through vacuum thermoforming, and that vacuum thermoforming as applied to thin multilayer films was not known in the art prior to the filing of the instant application.¹ The Examiner dismissed the foregoing argument as trying to ascribe patentable weight to the process limitation “formed from two vacuum thermoformed half-sections of a multilayer film.”¹

The Examiner ultimately stated that she would not allow the independent claims in their current form without substantial narrowing claim amendments. The undersigned communicated Applicant's intention to appeal the instant application to the Board of Patent Appeals and Interferences if necessary.

B. Response to Claim Rejections Under 35 U.S.C. §103

In the July 2, 2007 Office Action, claims 74-108 were rejected under 35 USC §103(e) as being unpatentable for obviousness over U.S. Patent No. 6,976,950 to Connors, et al. (hereinafter, Connors). Such rejections are traversed.

1. Law Regarding Obviousness

To support a rejection under 35 U.S.C. 103, the prior art reference(s) must teach all of the limitations of the claims. MPEP § 2143.03.

In considering a reference for its effect on patentability, the reference is required to be considered in its entirety, including portions that teach away from the invention under consideration. Simply stated, the prior art must be considered as a whole. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984) (emphasis added); MPEP § 2141.02. “It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what

¹ The novel and non-obvious character of applying vacuum thermoforming methods to thin multilayer films is demonstrated by issuance to Applicant of U.S. Patent No. 6,712,832, which broadly claims methods for manufacturing low-pressure balloons from thin film polymeric materials, including the steps of heating the thermoplastic polymeric material thin film to a sufficient temperature for vacuum

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such reference fairly suggests to one of ordinary skill in the art." *Application of Wesslau*, 353 F.2d 238, 241 (C.C.P.A. 1965); *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve*, 796 F.2d 443, 448 (Fed. Cir. 1986), cert. denied, 484 U.S. 823 (1987).

According to the recent U.S. Supreme Court decision in *KSR International Co. v. Teleflex Inc.*, 127 S.Ct 1727, 167 L.Ed.2d 705, 82 USPQ2d 1385 (April 30, 2007), the court did not disavow the previous "teaching, motivation or suggestion" or "TSM" test, but stated that such TSM text *should not be strictly applied* in determining obviousness. In connection with this point, the Supreme Court stated that:

"A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art. ... [Rather], it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant art to combine the [prior art] elements in the manner claimed." *KSR*, 82 USPQ2d at 1389.

It is fundamental to a proper rejection of claims under 35 U.S.C. § 103 that an examiner must present a convincing line of reasoning supporting the rejection. MPEP 2144 ("Sources of Rationale Supporting a Rejection Under 35 U.S.C. 103"), citing *Ex parte Clapp*, 227 USPQ 972 (Bd. Pat. App. & Inter. 1985). The Supreme Court in *KSR* affirmed the validity of such approach, stating that "**there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.**" *KSR*, 82 USPQ2d at 1396.

In *KSR*, the Supreme Court further confirmed that references that teach away from the invention are evidence of the non-obviousness of a claimed invention, (*KSR*, 82 USPQ2d at 1395, 1399) and reaffirmed the principle that a factfinder judging patentability "should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning."

thermoforming thereof, forming first and second half-sections for a balloon from the thin film by vacuum suction, and bonding the first and second half-sections together along edges thereof.

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2. Patentable Distinctions of Pending Claims Over Connors

Applicant hereby incorporates by reference all arguments made in its Response filed on April 23, 2007, and invites the Examiner to consider the evidence already made of record in the Declaration of Tilak Shah Under 37 CFR 1.132.

In the July 2, 2007 Office Action, the Examiner failed to point to any disclosure in Connors, or even allege that Connors discloses a balloon that is non-pillowed and spheroidal in shape when in an inflated state. In this regard, the rejections under 35 U.S.C. 103 are legally untenable, as they fail to teach all of the limitations of the claims, as required (pursuant to MPEP § 2143.03) to support an obviousness rejection under Section 103. It is noted that all of the pending claims require such "non-pillowed and spheroidal in shape when in an inflated state" limitation

With regard to the Examiner's prediction at the August 23, 2007 Interview that she would be readily able to find disclosure of balloon that was non-pillowed and spheroidal in shape, Applicant hereby renews its challenge to the Examiner to find a prior art reference embodying a spheroidal balloon that is:

not only (i) non-pillowed and spheroidal in shape when inflated,

***** *but also* *****

(ii) composed two half-sections of peripherally bonded multilayer film as claimed.

For purposes of construing the term "spheroidal," Applicant hereby offers the following definition provided by the Merriam-Webster's online dictionary at <http://www.m-w.com/dictionary/spheroidal>:

Main Entry: **spher·oid** ►

Function: **noun**

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: a figure resembling a sphere; also : an object of approximately spherical shape
- **spheroidal** **sfɪ-'roi-dəl/** *also spheroid adjective*

As indicated in Applicant's prior Response, vacuum thermoforming represents the only way known in the art for forming, from two peripherally bonded sections of non-elastic polymeric film, a balloon that in an inflated state is non-pillowed and spheroidal in shape. (Shah Decl., ¶ 9.)

Vacuum thermoforming as applied to thin multilayer films was not known in the art prior to the filing of the instant application. The use of vacuum thermoforming to fabricate balloons from polymeric sheets was pioneered by the same inventor as the present application, as evidenced by the issuance of U.S. Patent No. 6,712,832, which broadly claims methods for manufacturing low-pressure balloons from thin film polymeric materials, including the steps of heating the thermoplastic polymeric material thin film to a sufficient temperature for vacuum thermoforming thereof, forming first and second half-sections for a balloon from the thin film by vacuum suction, and bonding the first and second half-sections together along edges thereof. (Shah Decl., ¶ 13-14.) Notably, the application that matured into U.S. Patent No. 6,712,832 was not published (i.e., as U.S. Patent Application Publication No. 2003/0074017) until April 17, 2003 – which date is more than two weeks after the filing date of the instant U.S. Patent Application No. 10/815,282, and a month after the filing date of U.S. Patent Application No. 10/391,446 that matured into U.S. Patent No. 6,976,950 (Connors).²

Because vacuum thermoforming represents the only way known in the art for forming, from two peripherally bonded sections of non-elastic polymeric film, a balloon that in an inflated state is non-pillowed and spheroidal in shape (Shah Decl., ¶ 9), the determination by the USPTO that the balloon fabrication methods involving vacuum thermoforming claimed in U.S. Patent No. 6,712,832 are novel and non-obvious over the prior art – coupled with the lack of public disclosure of the subject matter of U.S. Patent No. 6,712,832 prior to the filing date of Connors – is consistent with the notion that Connors (which fails to mention vacuum thermoforming)

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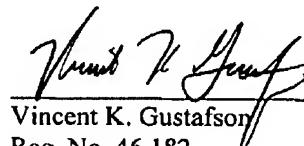
cannot be fairly read or interpreted to disclose a structure that can only be yielded by vacuum thermoforming, as embodied in the pending claims of the instant application.

Based on the foregoing arguments, on the Declaration of Tilak Shah Under 37 CFR 1.131 already made of record, and the arguments (incorporated by reference herein) made in Applicant's Response dated August 23, 2007, withdrawal of the claim rejections under 35 U.S.C. 103 premised on Connors is warranted, and is respectfully requested.

CONCLUSION

Based on the foregoing, all of Applicants' pending claims 74-108 are patentably distinguished over the art, and in form and condition for allowance. The examiner is requested to favorably consider the foregoing, and to responsively issue a Notice of Allowance. If any issues require further resolution, the examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss same.

Respectfully submitted,



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² Due to these facts and the operation of 35 U.S.C. 103(c), neither U.S. Patent No. 6,712,832 nor the corresponding U.S. Patent Application Publication No. 2003/0074017 may be used in any obviousness rejection of the claims of the instant application.